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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,826	12/03/2003	Andrew Thomas Forsberg	47563.0017	5521
57600 7590 07/24/2007 HOLLAND & HART LLP P.O. Box 11583 60 E. South Temple, Suite 2000 Salt Lake City, UT 84110			EXAMINER SEVERSON, RYAN J	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 07/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/726,826

Applicant(s)

FORSBERG ET AL.

Examiner

Ryan Severson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-39 and 41-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-39 and 41-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/7/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the arguments filed 07 May 2007.

Drawings

2. The drawings were received on 07 May 2007. These drawings are accepted.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 35 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).**
5. Regarding claim 35, the rejection stands for the same reasons set forth in paragraph 4 of the previous office action (paper no. 20061211) mailed 05 January 2007. See also the response to arguments section below.
6. Regarding claim 41, the tissue puncture is in a blood vessel (see figure 3).
7. Regarding claim 42, the anchor is moved away from and oriented transverse to the carrier tube (see figure 2).

8. Regarding claim 43, the nest includes one surface that is in contact with the anchor (see figure 1) and a second surface that is recessed in the carrier relative to the first surface. The second surface is considered recessed because it is both radially inward from the first surface and extends further in a proximal direction than the first surface.

9. **Claims 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681)** for the same reasons set forth in paragraph 5 of the previous office action (paper no. 20061211) mailed 05 January 2007.

10. **Claims 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti (5,814,073)** for the same reasons set forth in paragraph 6 of the previous office action (paper no. 20061211) mailed 05 January 2007.

11. **Claims 44-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).** Nash et al. (hereinafter Nash) reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32), and a sealing plug (30). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). The carrier tube includes one surface that is in contact with the anchor (see figure 1) and a second surface (the inner wall surface of carrier tube 102) that is adjacent the anchor. The second surface is considered recessed because it is both

Art Unit: 3731

radially inward from the first surface and extends further in a proximal direction than the first surface.

12. Regarding claim 45, the tissue puncture is in a blood vessel (see figure 3).

13. Regarding claim 46, the second surface is positioned adjacent an end of the anchor (see figure 1).

14. Regarding claim 47, the device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3).

15. Regarding claim 48, the anchor is moved away from and oriented transverse to the carrier tube (see figure 2).

16. **Claims 49 and 51-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).** Nash reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32), and a sealing plug (30). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). As shown in figure 1, there is a gap between the anchor and the nest. The gap extends in both longitudinal and transverse directions relative to the carrier tube.

17. Regarding claim 51, the tissue puncture is in a blood vessel (see figure 3).

18. Regarding claim 52, the gap is adjacent an end of the anchor (see figure 1).

Art Unit: 3731

19. Regarding claim 53, the device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3).

20. Regarding claim 54, the anchor is moved away from and oriented transverse to the carrier tube (see figure 2).

21. **Claims 55 and 57-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).** Nash reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32), and a sealing plug (30). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). The carrier tube includes a surface that is in contact with the anchor (see figure 1). There is also a recess (or gap) that extends further into the carrier tube than the first surface (see figure 1).

22. Regarding claim 57, the tissue puncture is in a blood vessel (see figure 3).

23. Regarding claim 58, the recess is positioned adjacent an end of the anchor (see figure 1).

24. Regarding claim 59, the recess extends in both longitudinal and transverse directions relative to the carrier tube.

25. Regarding claim 60, the anchor fills part of the recess (as in figure 1).

26. Regarding claim 61, the device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3).

27. Regarding claim 62, the anchor is moved away from and oriented transverse to the carrier tube (see figure 2).

28. **Claims 67-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (5,282,827).** Kensey et al. (hereinafter Kensey) reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32', see figures 34 and 35), and a sealing plug (30). The anchor is indented because of the area between the raised cap portions (32b) and the center of the anchor (see figure 35). The indent will cause a gap between the anchor and the carrier tube.

29. Regarding claim 68, the tissue puncture is in a blood vessel (see figures 16-18).

30. Regarding claim 69, the device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3).

31. Regarding claim 70, the anchor is moved away from and oriented transverse to the carrier tube (see figure 22).

32. **Claims 71 and 73-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).** Nash reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32), and a sealing plug (30). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). The carrier tube includes a surface that is in contact with the anchor (see

Art Unit: 3731

figure 1). There is also a recess (or gap) that extends further into the carrier tube than the first surface (see figure 1).

33. Regarding claim 73, the tissue puncture is in a blood vessel (see figure 3).

34. Regarding claim 74, the recess is positioned adjacent to one end of the anchor (see figure 1).

35. Regarding claim 75, the recess extends in both longitudinal and transverse directions relative to the carrier tube.

36. Regarding claim 76, the anchor fills part of the recess (as in figure 1).

37. Regarding claim 77, the device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3).

Claim Rejections - 35 USC § 103

38. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

39. **Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (5,662,681) as applied to claim 35 above, and further in view of Bonutti (5,814,073) for the same reasons set forth in paragraphs 7 and 8 of the previous office action (paper no. 20061211) mailed 05 January 2007.**

40. **Claims 50, 56, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (5,662,681) as applied to claims 49, 55, and 71 respectively, above, and further in view of Bonutti (5,814,073).** Nash reference does not disclose moving a tip of an insertion sheath into the gap to deploy the anchor. Attention is drawn to Bonutti reference, which teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the introducer sheath with resilient tips of Bonutti reference with the closure device of Nash reference to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

41. Furthermore, Nash reference states the closure device may be used with any typical introducer sheath (see column 4, lines 24-29). The tip of the insertion sheath would slide into a gap between the anchor and the nest because the tip of the sheath is resilient. The resiliency will cause the tips to conform to the shape it is compressed around, thereby filling the gap of Nash reference when that point is reached.

42. **Claims 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (5,662,681) in view of Bonutti (5,814,073).** Nash reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), an anchor (32), and a sealing plug (30). Nash reference further discloses the device is inserted into a percutaneous incision (see column 6, lines 57-60), the anchor is deployed (see column 6, lines 62-66), withdrawing the device from the incision (see column 7, lines 10-13), and tamping the sealing plug toward the anchor (see column 7, lines 43-51). The anchor and the carrier tube are in contact with one another.

However, Nash does not disclose moving a tip of an insertion sheath into the gap to deploy the anchor. Attention is drawn to Bonutti reference, which teaches an introducer sheath (30) may have a resilient tips (see column 6, lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the introducer sheath with resilient tips of Bonutti reference with the closure device of Nash reference to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

43. Furthermore, Nash reference states the closure device may be used with any typical introducer sheath (see column 4, lines 24-29). The tip of the insertion sheath would slide into a gap between the anchor and the nest because the tip of the sheath is

Art Unit: 3731

resilient. The resiliency will cause the tips to conform to the shape it is compressed around, thereby filling the gap of Nash reference when that point is reached.

44. Regarding claim 64, the tissue puncture is in a blood vessel (see figure 3).

45. Regarding claim 65, the device includes a filament (34) that couples the sealing plug and the anchor together (see figures 2 and 3).

46. Regarding claim 66, the anchor is moved away from and oriented transverse to the carrier tube (see figure 2).

Response to Arguments

47. Applicant's arguments filed 07 May 2007 have been fully considered but they are not persuasive. Applicant has argued that neither Nash et al. or Bonutti disclose a multi-level nest. Examiner notes that nowhere in the specification has applicant specifically given a strict definition of the term "multi-level nest." Therefore, the claims are interpreted as broadly as is reasonable, in light of the specification. This does not mean, however, that the claims are limited by unclaimed limitations that are only present in the specification. In the instant case, quite simply, a multi-level nest must have more than a single level. Therefore, the previous rejections of claims 35-39 stand as previously communicated and new claims 41-77 are rejected as described above.

Conclusion

48. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

49. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

50. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 9:00 - 5:30.


51. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

52. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.S.

Ryan Severson
July 18, 2007


LOAN H. THANH
PRIMARY EXAMINER